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University Health Board

Children's Information Sheet

Invitation to screening visit

FULL STUDY TITLE: Respiratory Health Outcomes in Neonates (RHINO)

CHIEF INVESTIGATOR: Professor Sailesh Kotecha (University Hospital of Wales, Heath Park, Cardiff)

What is a research study? Why is this study being done?

A research study is what you do when you want to learn about something or find out something new. In our other research we have found that children who were born early (prematurely) sometimes have breathing problems. We are doing this study to learn more about the reasons why.



Why was I asked to take part?

You were chosen to take part because you were not born early and your parent or carer told us as part of a survey that you would be happy to think about taking part. This part of the research study will involve about 1000 children in Wales.

Did anyone else check the study is OK to do?

Before any study is allowed to happen, it has to be checked by a group of people called an Ethics Committee. The Ethics Committee is a group of experts and ordinary people who look at studies very carefully to decide whether they are OK to do. An Ethics Committee has looked at this study and decided it is OK.

Do I have to say yes?

No – not at all. It's up to you!
Just say if you don't want to take part.
Nobody will mind.

If you do take part, you will need to write your name on a form called an 'assent form'. This form is to say that you understand the study and what will happen if you join. You will be given your own copy of this form to keep as well as this information sheet.



What will I need to do and how long will it take?

We would like a study nurse or doctor to come and visit you and your parents or carers at home to talk to you about the research and do some tests. We think all this will take about an hour. If you say yes to joining the study, you will need to answer some questions and tell the doctor or nurse about your breathing. They will check you over to make sure that you are well enough to be in the study. They will also measure your growth, development, and how much muscle and fat you are made of. All of these tests need you to stand still and take just a few moments.

Next, the doctor or nurse will measure how much air you can breathe in and out of your lungs by asking you to do some blowing tests.

For some of the tests you will need to blow the air out of your lungs in one big breath; for other tests you will just need to breathe quietly. You will have time to practise each test so you can do your best. After the tests the doctor or nurse will give you a small amount of medicine with an inhaler, and, after a few minutes ask you to do one of the blowing tests again to see if the medicine had an effect.

Last of all, the nurse or doctor will ask if you would mind us having a sample of your urine (wee). We would also like to take a sample of your saliva (spit), but only if your parents or carers think this is OK. These can be tested to help us understand more about reasons for breathing problems.



Will joining in the study help me?

Since you were not born early taking part will not help you, but what we learn from the study might help other boys and girls with breathing problems who are born early.

Who will know that I am in the study?

The study doctor and nurse who are taking care of you will know, as well as your parents or carers.

How will the information about me be kept private?

Everything you tell us is private. The only time we would ever tell somebody what you have said is if something made us worried about you. All information collected for this study will be kept safely on the computer or as paper records. Of course, you can tell your family and friends about the study if you want to.





What happens if there is a problem with the study?

If you think there are any problems with the study or if you have any worries about it you can tell your parents or carers. You can also tell the study nurse or doctor. They will do their best to answer your questions. If you are still unhappy you can talk to someone else. Your parents or carers will probably be the best people to talk to.

What if I don't want to do the study anymore?

If you want to stop the study at any time, just tell your parents or carers, study doctor or nurse. They will not be cross with you. If you say no or want to stop the study at any time it will not change the way the doctors and nurses will look after you.

What will happen to the results of the study?

We will write reports for the doctors and nurses who look after children with breathing problems. The results will also be written in special magazines (scientific journals). No-one will know that they are your results because your name will not be written on them. You will be able to see the results on the study website in the future.

What shall I do now?

Now you know about the study you need to think about whether you want to join or not.

Who can I talk to for more information?

If you have any questions at all, at any time, please contact:

The RHiNO team by

telephone (029 2074 4187)

or email (rhino@cardiff.ac.uk)

Further information is available at our website
<http://rhino-health.org>.

**Thank you for reading this information sheet.
We hope you have found the information helpful.**



Children's Assent Form

RHINO: Respiratory Health Outcomes in Neonates (Part 1)

Young person (or, if unable, parent/guardian on their behalf) to circle all they agree with:

Have you read (or had read to you) the information about this study?	Yes	No
Has a doctor or nurse explained this study to you?	Yes	No
Do you understand what this study is about?	Yes	No
Have you asked all the questions you would like to?	Yes	No
Have all your questions been answered in a way you understand?	Yes	No
Do you know that it's OK to stop taking part at any time?	Yes	No
Are you happy to take part in this study?	Yes	No
Are you happy to give a sample of you saliva (spit)?	Yes	No

If the answer to any question is 'No', or you don't want to take part, don't sign your name.

If you DO want to take part, please write your name and today's date below:

Your name:

Date:

Your parent/guardian must also write their name here too if they are happy for you to take part:

Sign:

Print:

Date:

The doctor or nurse who explained the study needs to sign as well:

Sign:

Print:

Date:

Original for case notes, 1 copy for parent/guardian, 1 copy for investigator site file